

**ENVIRONMENTAL PROTECTION AGENCY
ENVIRONMENTAL TOBACCO SMOKE RISK ASSESSMENT
AND POLICY GUIDE**

I. THE EPA RISK ASSESSMENT ON ETS

The draft ETS risk assessment is the first one ever conducted by EPA that is based entirely on epidemiologic evidence. ETS epidemiologic studies involve the comparison of lung cancer risk between nonsmokers married to nonsmokers and nonsmokers married to smokers. A review of the published ETS-lung cancer studies reveals the following:

- . A total of 24 studies are listed in the ETS report. Of those, only five reported a statistically significant association.
- . Of nine existing U.S. studies, none reported a statistically significant association between spousal smoking and lung cancer in nonsmokers.
- . The most recent ETS - lung cancer study to appear in the scientific literature found no association between ETS and lung cancer. When the new study is added, ETS exposure is not statistically associated with risk of lung cancer.
- . Despite the fact that the risk assessment is used to form the basis for EPA's workplace smoking policy recommendations, only seven of the ETS studies have even attempted to examine workplace exposure to ETS. Of those seven, only one reported a statistically significant association.
- . All of the existing epidemiologic studies of ETS and lung cancer reflect a number of flaws which complicate their interpretation. Among them:
 - a) Inadequate Exposure Classification: Existence or degree of actual nonsmoker exposure is unknown.
 - b) Inadequate Attention to Confounding Factors: Virtually none of the ETS-lung cancer studies have adequately controlled for the appropriate confounding factors. Potential confounding factors include alcohol consumption, occupational exposures and socio-economic status.

Meta analysis, a statistical procedure where a number of studies are combined to produce a single estimate of relative risk, generally is used when studies standing alone lack sufficient power to justify the interpretation of an association. The meta analysis conducted in the EPA risk assessment is flawed from a number of perspectives:

- a) Although a total of 22 case-control studies on ETS and lung cancer have been conducted to date, only 19 were included in the EPA's meta analysis of ETS studies. The three studies omitted reported no statistically significant association between marriage to a smoker and risk of lung cancer.
- b) The draft EPA report makes no effort to calculate and compare analyses from U.S. versus non-U.S. studies, despite the fact that the risk assessment purports to estimate risk for the U.S. population. Experts who conducted a meta analysis for the U.S. studies alone reported no statistically significant association between ETS and lung cancer.
- c) The meta analysis does not include the most recent data on ETS and lung cancer.

II. THE FACTS ABOUT THE SCIENTIFIC ADVISORY BOARD (SAB) REVIEW

BACKGROUND

The EPA's Science Advisory Board met in December 1990 to consider the draft ETS risk assessment and policy guide. The committee chairman announced that the group had reached a consensus that ETS is a cause of lung cancer in nonsmokers. On the issue of respiratory effects in children, the chairman maintained that EPA's conclusion that ETS is associated with respiratory effects was not sufficiently strong. The chairman and other panel members recommended the conclusion of a causal relationship between ETS and respiratory disease in children.

It was not specifically stated that the panel agreed to designate ETS as a Group A carcinogen. That designation is implied, however, by the conclusion that the data are sufficient to justify defining ETS as a cause of lung cancer in adults and respiratory disease in children.

On the policy guide, the panel approved most of the health effects discussions in the draft, but noted that EPA should not make claims about health effects that are not addressed in the risk assessments.

Despite its agreement with the risk assessment's conclusions, the panel overall was quite critical of the report and recommended a number of revisions that will require significant additional work.

The panel did not agree that EPA had established convincingly the conclusions that ETS is a cause of lung cancer in adults and respiratory disease in children. Instead, EPA was instructed to revise the report to "make that case."

DISCUSSION POINTS

The SAB's anticipated conclusions regarding the causal association in the risk assessment are tentative, not final.

The panel's conclusions on the risk assessment can be described only as irrational, given the fact that the members acknowledged that the data presented in the report do not support the conclusions made and that they agreed with virtually every criticism raised concerning the documents by the industry presenters.

Despite press reports to the contrary, the SAB panel members chosen to review the documents were not biased in favor of the tobacco industry.

a) At the request of the Agency, The Tobacco Institute proposed a number of eminent scientists with no stake in the outcome of the review for inclusion on the panel. None of the scientists suggested by The Tobacco Institute was contacted to participate.

b) In contrast, three candidates proposed by anti-smoking activists are on the panel.

Despite the claims made in the EPA's policy guide, the risk assessment provides no rational basis for policies restricting smoking in the workplace. Of seven studies that have examined exposure to ETS in the workplace and lung cancer, only one has reported a statistically significant association. The largest ETS - lung cancer study ever conducted in the U.S. failed to demonstrate an association between workplace exposure and risk of lung cancer.